

PATENT COOPERATION TREATY

10/542413

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)Applicant's or agent's file reference
see form PCT/ISA/220**FOR FURTHER ACTION**
See paragraph 2 belowInternational application No.
PCT/CA2004/000016International filing date (day/month/year)
06.01.2004Priority date (day/month/year)
14.01.2003International Patent Classification (IPC) or both national classification and IPC
A61F2/34, A61C8/00, A61F2/28, A61F2/46Applicant
LOCOCO, Michael

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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JC20 Rec'd PCT/PTO 13 JUL 2005

International application No.
PCT/CA2004/000016WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
- ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/CA2004/000016

Box No. II Priority

1. ☒ The following document has not been furnished:

- ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).
- ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/CA2004/000016

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 10-18, 26-35

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 10-18,26-35
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/CA2004/000016

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-9, 19-25

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement.

1. Statement

Novelty (N)	Yes: Claims	3,4,6,19-25
	No: Claims	1,2,5,7-9
Inventive step (IS)	Yes: Claims	19-25
	No: Claims	3,4,6
Industrial applicability (IA)	Yes: Claims	1-9,19-25
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item IV

Lack of unity of invention

1. This Authority considers that there are 3 inventions covered by the claims indicated as follows:

I: Claims 1-9, 19-25 directed to a bone implant and associated template means, the bone implant comprising:

- a core having a first end wall, a second end wall and defining a centreline extending centrally of and between said end walls;
- at least two axially elongated projections extending from and along said core disposed at uniform circumferential spacing from each other about the centreline and having a rounded contour when viewed in the axial direction of the core; said core and said projections being dimensioned to contact inner wall sections of a socket formed in bone.

II: Claims 10-18, 26-29, 30-32 and 33 directed to a bone implant and associated template means, the bone implant comprising:

- a core having a first end wall, a second end wall and defining a centreline extending centrally of and between said end walls;
- at least two axially elongated stems extending from said second end of the core at diametrically opposed locations disposed near a periphery of the second end wall and having a rounded contour when viewed in the axial direction of the core; said core and said stems being dimensioned to contact inner wall sections of a socket formed in bone.

III: Claims 34 and 35 directed to a drill bit for use in forming a socket for a bone implant, said drill bit comprising, in combination:

- a shank;
- a cylindric stem coaxial with the shank and terminating in a rounded tip;
- a pair of radially projecting, opposed cutting blades.

The common concept linking independent claims 1 and 10 is a bone implant comprising a core with an axis, said core being dimensioned to contact an inner wall of a socket formed in bone. This concept, however, is well known in the

relevant state of the art (see, for example, US-A-5766009). There is no common "special technical feature" in terms of Rule 13.2 PCT linking claims 1-9, 19-25 with claims 10-18, 26-29, 30-32, 33. Thus, the requirement of unity according to Rule 13.1 PCT is not fulfilled.

Similarly, there is no common concept and consequently no common "special technical feature" in terms of Rule 13.2 PCT linking claim 1 with claims 34 and 35. Thus, again, the requirement of unity according to Rule 13.1 PCT is not fulfilled.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. Reference is made to the following documents:

D1: DE 35 33 432 A (ALLOPLANT BURDORF & LAUCHART O) 26 March 1987
D2: US-A-5 766 009 (JEFFCOAT ROBERT L) 16 June 1998
D3: WO 00/74607 A (OSTEOTECH INC) 14 December 2000
D4: US-A-5 013 242 (PREZMECKY LASZLO) 7 May 1991
D5: DE 198 16 832 C (AESCULAP AG & CO KG) 20 January 2000

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 2, 5, 7-9 is not new in the sense of Article 33(2) PCT.

- 3.1 The document **D1** discloses (the references in parentheses applying to this document): a core (10) having a first end wall, a second end wall and defining a centreline (11) extending centrally of and between said end walls, and a circumferential side wall portion parallel and extending between said end walls; at least two axially elongated projections (14), extending from and along said core, being disposed at a uniform circumferential spacing from each other about the centreline, and having a rounded contour when viewed in axial direction of the core (10); said core (10) and said projections (14) being dimensioned to contact inner wall sections of a socket formed in bone and having a predetermined size and configuration compatible with that of the implant, when the implant has been

- tapped into the socket (see the abstract, column 2, lines 41-60 and the figures). In addition, document D1 anticipates the subject-matter of dependent claims 5 and 7-9 (see the abstract, column 2, lines 41-60 and the figures).
- 3.2 The same result with respect to the lack of novelty of claims 1, 7-9 is also obtained with document D2 (see the abstract, column 4, lines 32-49 and figure 2C), document D3 (see page 12, line 18 to page 13, line 11, page 13, line 18 to page 14, line 2 and figures 1, 3, 4 and 11), document D4 (see the abstract and figures) and document D5 (see the abstract and figures 5 and 10). Furthermore, document D2 discloses the subject-matter of claim 2 (see the abstract, column 4, lines 32-49 and figure 2C).
- 3.3 Therefore, claims 1, 2, 5, 7-9 are not novel and as such do not meet the criteria of Article 33(2) PCT.
4. Claims 3, 4 and 6 concern slight constructional changes in the bone implant of claim 1 which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of claims 3, 4 and 6 appears to lack an inventive step contrary to Article 33(3) PCT.
5. Claim 19 concerns a template means for forming an implant receiving socket, for which no relevant prior art is cited in the International Search Report.
- 5.1 The subject-matter of claim 1 is therefore new (Article 33(2) PCT).
- 5.2 The problem to be solved by the invention of claim 19 is how to prepare a socket in bone to receive a bone implant, whereby a firm securement to bone tissue is provided.
- 5.3 The solution to this problem proposed in claim 19 of the present application is considered as involving an inventive step (Article 33(3) PCT) since there is no document in the available prior art which suggests the combination of features described in claim 19.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/CA04/00016

- 5.4 Claims 20-25 are dependent on claim 19 and as such also meet the requirements of the PCT with respect to novelty and inventive step.
6. Reference signs should have been used throughout the claims (Rule 6.2(b) PCT).
7. To meet the requirements of Rule 5.1(a)(ii) PCT, the documents D1, D2, D3, D4 and D5 should have been identified in the description and the relevant background art disclosed therein briefly discussed.